Section 5 510(k) Summary

DEC 12 2013

This 510(k) summary is being submitted in accordance with 21 CFR § 807.92.

5.1 General Information

Establishment	Siemens Medical Solutions USA, Inc. 51 Valley Stream Parkway Mail Code D02 Malvern, PA 19355, USA Registration Number: 2240869
Manufacturer	Siemens AG Henkestrasse 127 D-91052 Erlangen, Germany Registration Number: 3002808157
Contact Person	Ms. Nadia Sookdeo Regulatory Affairs Technical Specialist Siemens Medical Solutions USA, Inc. 51 Valley Stream Parkway Mail Code D02 Malvern, PA 19355, USA Phone: (610) 448-4918 E-mail: Nadia.Sookdeo@siemens.com
Device Name	MAGNETOM Aera/Skyra
CFR Code	21 CFR § 892.1200
Classification	Class II
Product Codes	LNH
Classification Name	Magnetic Resonance Diagnostic Device (MRDD), Emission Computed Tomography System, MR Coils

5.2 Information Supporting Substantial Equivalence

DEVICE DESCRIPTION

The MAGNETOM MR system is a magnetic resonance device (MRDD) producing transverse, sagittal, coronal, and oblique sectional images, spectroscopic images and/or spectra, and displaying internal structure and/or function of the head, body, or extremities. Other physical parameters derived from the images and/or spectra may also be produced.
The MAGNETOM system may also be used for imaging during interventional procedures when performed with MR compatible devices such as in-room displays and MR-safe biopsy needles.

The software *syngo* MR D13A is the latest software for the Siemens MAGNETOM scanners including software sequences, applications, coils and other hardware for the MAGNETOM scanners. This software was previously cleared under K121434.

New scanners are manufactured with *syngo* MR D13A; existing scanners can be upgraded to this software version.

This filing describes additional local coils intended to be used with the MAGNETOM Aera and MAGNETOM Skyra.
For MAGNETOM Skyra the Head/Neck 64, the Breast 18 and the Body 18 long are new coils. For MAGNETOM Aera the Breast 18 and the Body 18 long are new coils.

INTENDED USE

The MAGNETOM MR system [Aera / Skyra] is indicated for use as a magnetic resonance diagnostic device (MRDD) that produces transverse, sagittal, coronal and oblique cross sectional images, spectroscopic images and/or spectra, and that displays the internal structure and/or function of the head, body, or extremities.

Other physical parameters derived from the images and/or spectra may also be produced. Depending on the region of interest, contrast agents may be used. These images and/or spectra and the physical parameters derived from the images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

The MAGNETOM MR system [Aera / Skyra] may also be used for imaging during interventional procedures when performed with MR compatible devices such as in-room displays and MR-Safe biopsy needles.

NONCLINICAL TESTS

The following performance testing was conducted on the subject device:

- The coils were tested for SNR, image uniformity, and heating per applicable NEMA and IEC standards.

The test results demonstrate that the device performs as intended and is thus substantially equivalent to the predicate device to which it has been compared.

CLINICAL TESTS

There were no clinical tests conducted to support the subject device and the substantial equivalence argument, however sample images of the now local coils of the subject devices are provided to support the descriptions in Section 11.

SUBSTANTIAL EQUIVALENCE

The MAGNETOM Aera/Skyra with software *syngo* MR D13A including the additional local coils Head/Neck 64, Breast 18 and Body 18 long is substantially equivalent to the following predicate device, described in Table 1.

Table 1: Predicate device for MAGNETOM Aera/Skyra

Predicate Device Name	FDA Clearance Number	FDA Clearance Date	Main Product Code
Software *syngo* MR D13A for the MAGNETOM Systems Aera / Skyra / Avanto / Verio	K121434	Nov 5, 2012	LNH

There is no system change and no software change. The only difference between the subject and the predicate device are the additional new local coils for the systems.

SAFETY AND EFFECTIVENESS

The device labeling contains instructions for use and any necessary cautions and warnings to provide for safe and effective use of the device.

Risk Management is ensured via a risk analysis in compliance with ISO 14971:2007 to identify and provide mitigation to potential hazards beginning early in the design cycle and continuing throughout the development of the product. Siemens Medical Solutions USA, Inc. and Siemens AG adhere to recognized and established industry standards, such as the IEC 60601-1 series, to minimize electrical and mechanical hazards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 12, 2013

Siemens Medical Solutions USA, Inc.
% Ms. Nadia Sookdeo
Regulatory Affairs Technical Specialist
51 Valley Stream Parkway
Mail Code D02
MALVERN PA 19355

Re: K133435
Trade/Device Name: MAGNETOM Aera/Skyra *syngo* MR D13A
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: November 7, 2013
Received: November 8, 2013

Dear Ms. Sookdeo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

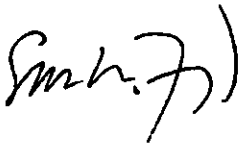
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)* k133435

Device Name
MAGNETOM Aera Skyra syngo MR D13A with additional local coils

Indications for Use *(Describe)*

The MAGNETOM MR system [Aera · Skyra] is indicated for use as a magnetic resonance diagnostic device (MRDD) that produces transverse, sagittal, coronal and oblique cross sectional images, spectroscopic images and or spectra, and that displays the internal structure and or function of the head, body, or extremities.

Other physical parameters derived from the images and or spectra may also be produced. Depending on the region of interest, contrast agents may be used. These images and or spectra and the physical parameters derived from the images and or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

The MAGNETOM MR system [Aera · Skyra] may also be used for imaging during interventional procedures when performed with MR compatible devices such as in-room displays and MR-Safe biopsy needles.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 501 Subpart D) ☐ Over-The-Counter Use (21 CFR 501 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*